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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,153	09/29/2005	Annette Martin	UTSG:272US	7019
32425 7590 01/31/2008 FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			EXAMINER CHEN, STACY BROWN	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 01/31/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,153

Applicant(s)

MARTIN ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-9, 11, 13, 17-21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-9, 11, 13, 17-21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/21/05.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I, embodiment C, filed November 12, 2007 is acknowledged. The claims have been amended in the November 12, 2007 response. Although only claims 6, 7, 17, 18, 21 and 23-26 read on the elected invention, claims 4, 5, 8, 9, 11, 13, 19 and 20 will be rejoined with the elected invention for examination on the merits. Claim 27 is withdrawn from consideration being drawn to non-elected subject matter.

Specification

2. The specification is objected to because the status of parent application USSN 10/198,359 should be updated. Further, it is noted that in the preliminary amendment of January 3, 2005, the first paragraph of the specification (page 1) was amended to include a reference to the PCT application that claims priority to the US application referenced above. Technically speaking, a PCT cannot be a continuation-in-part of a US application. More appropriate language would be, "The present application is a national phase application under 35 U.S.C. 371 of International Application No. PCT/US2003/021002 filed July 2, 2003, which claims priority to U.S. Patent Application Serial Number 10/198,359 filed on July 3, 2002", etc.

Drawings

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figure 9 contains captions that are illegible. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claims Summary

4. The claims are drawn to an isolated polynucleotide comprising a chimeric GBV-B (hepatotropic flavivirus) polynucleotide that encodes a virus comprising domain III of an HCV (Hepatitis C Virus) 5' NTR. (GB virus is named after the patient from whom it was originally isolated/discovered.) In one embodiment, the 5' NTR domain Ib of GBV-B is deleted.

In other embodiments, various combinations of domain III along with either domain I, domain II or domain IV of HCV 5' NTR are constructed. Additionally, the polynucleotide sequence may further comprise structural or non-structural HCV coding regions. The chimeric polynucleotide is DNA or RNA. The polynucleotide is in a viral expression construct and may further comprise the Ib region deletion. The construct is a plasmid or a virus.

It is noted that, according to the specification, Applicant has elucidated the 3' terminal sequence of GBV-B, essential for the construction of an infectious molecular GBV-B clone (page 3, lines 6-16).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of claim 26 does not appear to differ from claim 21, since the viral *expression* construct of claim 21 is designed to express a chimeric GBV-B/HCV virus. The

phrase "further defined as a construct for the expression of a chimeric GBV-B/HCV virus" recited in claim 26, does not add any structural limitation to claim 21. Clarification is required.

Double Patenting

6 A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 6 and 21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 and 20 of prior U.S. Patent No. 7,141,405. This is a double patenting rejection. The scope of the instant claims is identical to the scope of the patented claims.

Obviousness-Type Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4, 5, 7-9, 11, 13, 17-20 and 23-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-19 and 21-23 of U.S. Patent No. 7,141,405. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are a species of the instant genus claims. The patented claims specify that at least part, but not all of a 5' NTR sequence (domains I-IV) is from HCV. The instant claims do not have this limitation.

Conclusion

8. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number:
10/520,153
Art Unit: 1648

Page 6

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 1-28-2008
Primary Examiner, TC1600